

# **EXHIBIT B**



**Bringing Focus to Women's Health**

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Infertility, ovarian cancer pipeline

# Opportunity



nVision is an early-stage medical device company developing unique access platform technology for the reproductive system that will address two substantial unmet needs in women's health

- Accurate diagnosis of the leading cause of **infertility**
- Early detection of **ovarian cancer**

Seed round secured, POC complete. Now raising \$4 million Series A round (\$3.75 committed) to attain regulatory approval

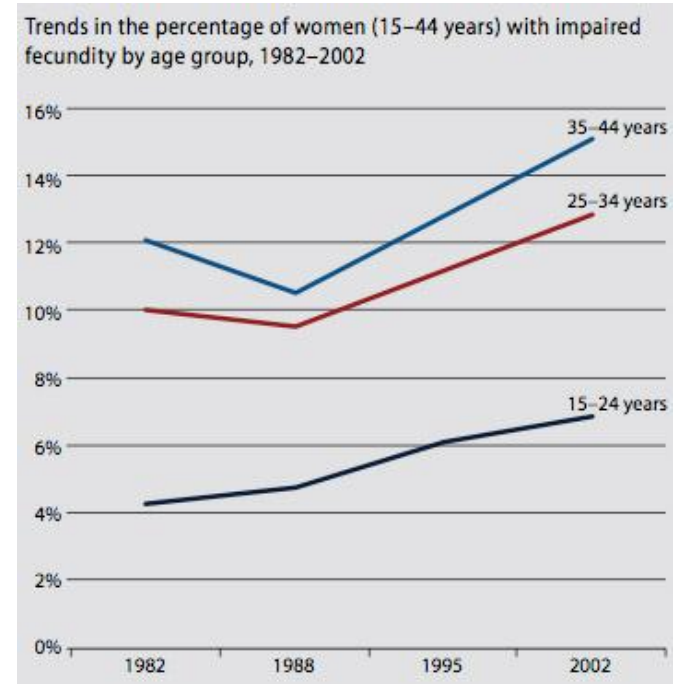




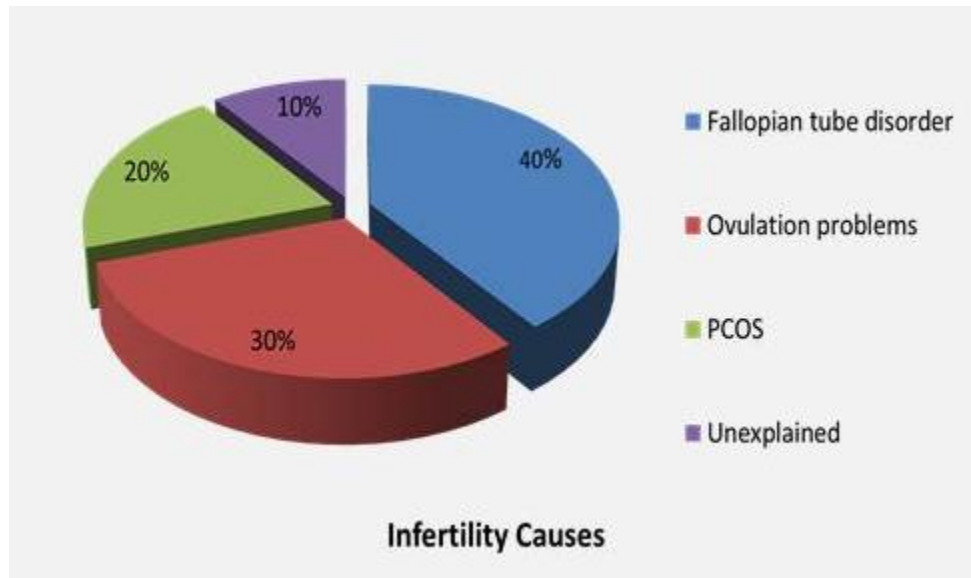
# Infertility

# Infertility Space

- \$5 billion market in US alone
- Impacts over 6 million US women
- Rapidly increasing in developed and developing countries



Fallopian tube blockage is the leading cause of infertility

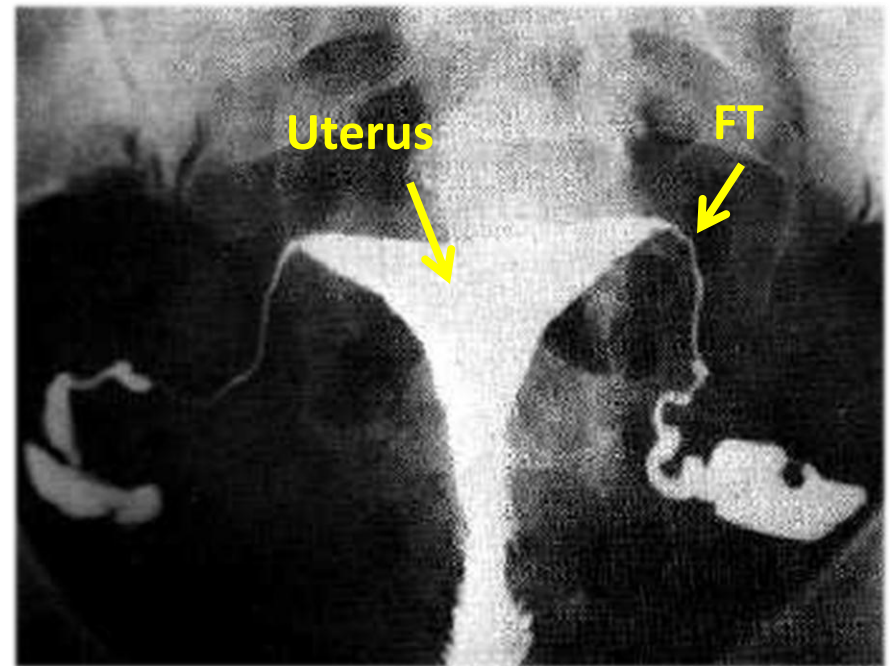


# The Clinical Need

Need for an accurate & real-time method of diagnosing fallopian tube blockage and disease *in the office* of the gynecologist

## We aim to replace the Hysterosalpingogram (HSG)

- Extremely inaccurate
- Painful for the patient
- Exposes a patient to radioactivity, linked to bladder cancer
- No reimbursement to gatekeeper of patient and inconvenient
- No significant improvement since 1914



# Previous Product Shortcomings

Conceptus Inc. and Imagyn both attempted to create an endoscopic device in 1998 but faced hurdles

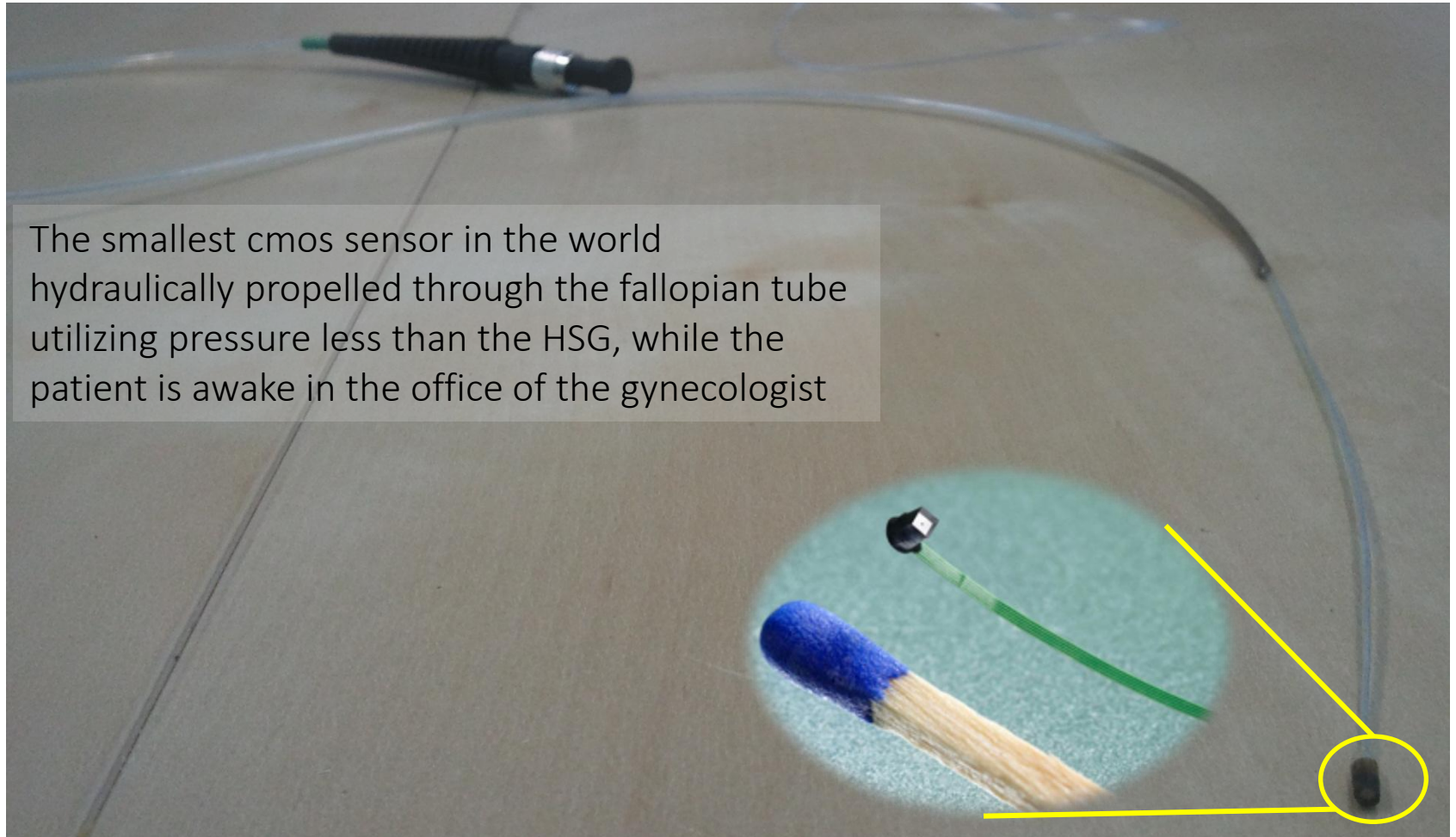
- Complex procedure –accessing the fallopian tube within the uterus
- Fallopian tube perforation caused by lack of tactile feedback
- Minimal risk to patient safety but causes delay in procedure & conception
- Competition – HSG & FemVue procedure (technique done under ultrasound)



# The Product



The solution is a real-time visualization system which can be easily used in the office of the reproductive specialist.



The smallest cmos sensor in the world  
hydraulically propelled through the fallopian tube  
utilizing pressure less than the HSG, while the  
patient is awake in the office of the gynecologist



# Intellectual Property

Several **patents pending** on unique catheter characteristics and methods of use

- To decrease the risk of perforation
- To increase the quality of the images
- Additional novel therapeutic concepts

PCT Search Report – NO prior art found for 70 claims in our application



Not the final design,  
but another over the  
wire approach

# Feasibility Study- Complete

A post-hysterectomy human tissue study to demonstrate ability of product

Collected uterus and fallopian tube tissue directly after hysterectomy, relevant structures still intact (total of six samples)

Demonstrated:

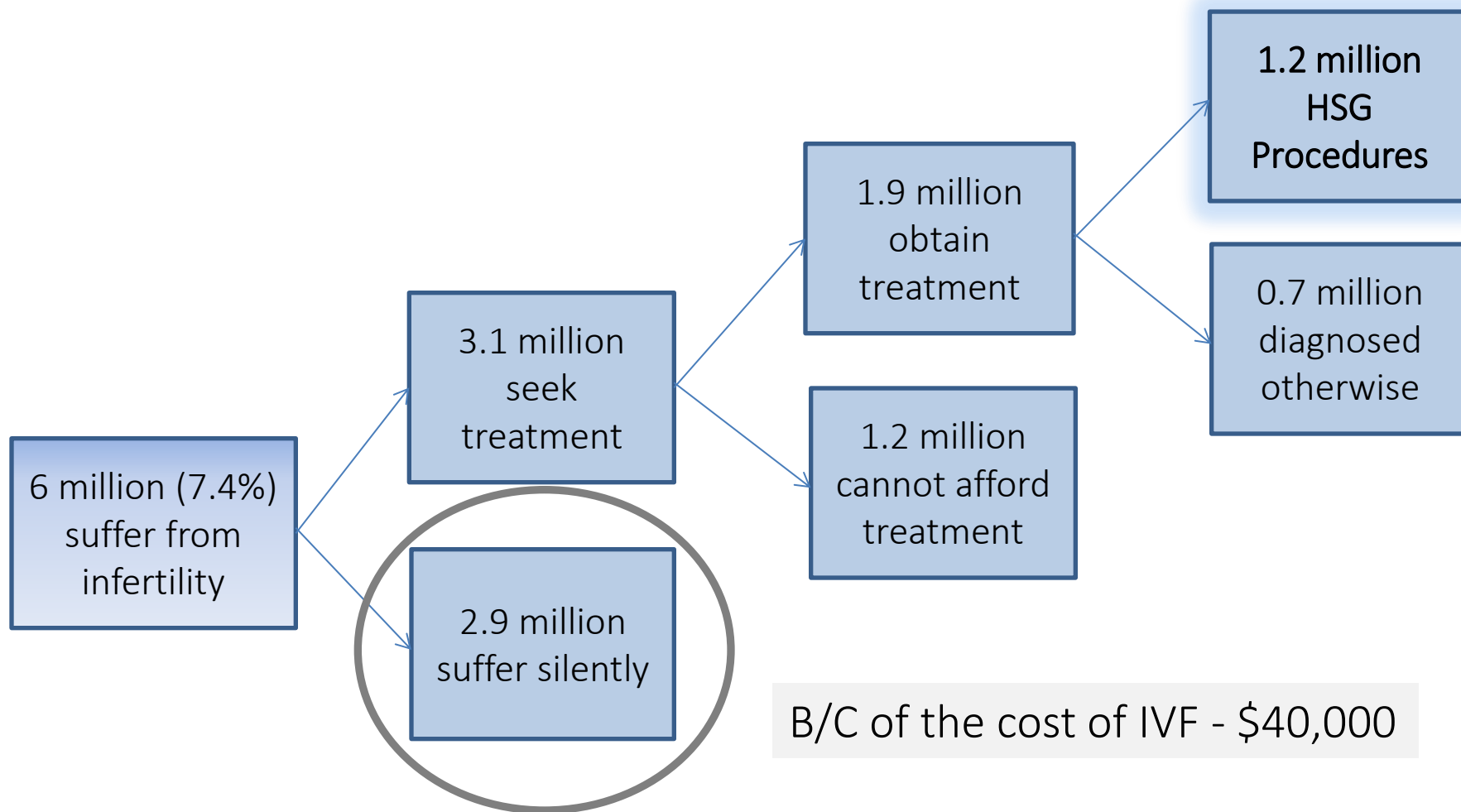
- Quality of images
- Hydraulic propulsion of device
- No fallopian tube damage



# The Market



1.2 million tubal diagnostic procedures conducted annually in the US.



# Reimbursement



Majority of Infertility treatments are self pay

- HSG average **\$1000** per procedure with variation based on geographic location
- Codes exist for female infertility of tubal origin AND diagnosis of tubal patency
- Reimbursement specialist currently working on best combination of codes

# Addressable Market



# Regulatory Strategy

In US: 510(k) approval as a Class II device with no to *limited* clinical trials  
In Europe: Class IIa device with *NO* clinical trials

Cindy Domecus - over 20 years of experience dealing directly with the FDA. Was VP of Regulatory affairs for Conceptus (filed for devices that are our predicates)

- The 510(k) precedent for substantial equivalence (SE) is **well established** for the intended use of the falloposcope to selective salpingography (SSG)
- Three devices have previously been 510(k) cleared by FDA with this indication
- FDA has published a guidance document for this device and indication as Class II via 510(k) premarket notification



# Clinical Studies



## 510(k) and CE mark - no clinical data

Measure of substantial equivalence is image quality and force required to navigate the fallopian tube – K962587, Conceptus. If pushback, 20-50 person trial – budget assumes up to 100 patients given new regulatory climate



### **nVision's Lead Clinical Advisor**

Lynn Marie Westphal, MD

Director of Women's Health, Stanford

Clinical focus: Fertility, Reproductive Medicine,  
Gynecology, Obstetrics and Gynecology

Dr. William Keye  
University of Utah  
Director of IVF  
30+ years of experience

Dr. Viviane Connor  
Cleveland Clinic  
Founder and Director,  
Minimally Invasive Surgery

Dr. Jim Tsaltas  
President Australasian  
Gynecological Endoscopy &  
Surgery Society (AGES)

# Development Plan



Regulatory approval granted after two years and \$4 million in funding.

- Proof of Concept: Achieved within first year utilizing \$200,000
- CE Mark & 510 (k) approval: Achieved in year three utilizing an additional \$4 million.
- IF NEEDED - Commercially available: by the third year, entailing an additional \$2 million (distribution channels) or \$6 million (build small sales team).
- Profitability: by year five, nVision will be profitable with a cumulative investment of \$10 million
- Revenue of 45 million by year 6

**Potential**

**Exit**



Years	2012	2013	2014	2015	2016	2017
<b>Revenue (\$)</b>				1,028,000	13,750,000	44,703,000
<b>Expenses (\$)</b>	196,000	1,717,133	2,168,414	6,526,070	11,514,508	16,983,711
<b>Pretax loss/profit (\$)</b>	(196,000)	(1,717,133)	(2,168,414)	(5,498,070)	2,235,491	27,719,288

# Potential Acquirers

Device companies with women's health arm or endoscopy companies



Detailed operating and financing plan available upon request

# Deal Terms

- Virtual company – only one full time employee until approval
  - Low burn
  - Risk mitigation strategy
- This is the business model of our lead investor, Catalyst Health Ventures
- \$4 mil raise - \$4.5 pre money valuation
- 1x liquidation, participating preferred, drag along

# The Team

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Surbhi Sarna, Chief Executive Officer

## **Research and Development**

Rajan Patel, Acting VP of R&D

Serge Bierhuizen, Lead Optical Engineer  
+ team of 3 mech. engineers

## **Advisors**

Karen Drexler, Advisor

Lynn Westphal MD, Lead Clinical Advisor

Al Chin, M.D. & Innovator

## **Consultants**

Theresa Brandner, Regulatory Consultant

Ben Bedi, IP Attorney

## **Investors & Board**

Chairman

**Anula Jayasuriya MD PhD MBA**

Catalyst Health Ventures

**Darshana Zaveri**

LMN Ventures

**Corinne Nevinny**

(Most recently President of Global Operations of  
Edwards Life Science)

Draper Fisher Jurvetson, Draper Associates

Tim Draper



# Thank you

## **Available documents**

- Executive summary and slide deck
- FAQ
- Detailed operating plan and financial projections
- Market analysis and sales strategy projection
- Due diligence documentation from Astia Angels
- Term sheet

Begin references

# Market References

Parameter	Percent	Resulting Number	Reference									
US population		307,006,550	<a href="http://quickfacts.census.gov/qfd/news.html">http://quickfacts.census.gov/qfd/news.html</a>									
% women	50.7%	155,652,321	<a href="http://quickfacts.census.gov/qfd/news.html">http://quickfacts.census.gov/qfd/news.html</a>									
% child bearing	52.1%	81,094,859	<a href="http://www.census.gov/ipc/prod/wp02/wp-02004.pdf">http://www.census.gov/ipc/prod/wp02/wp-02004.pdf</a>									
% infertile	7.4%	6,001,020	Stephen EH, Chandra A. Use of infertility services in the United States: 1995. Fam Plann Perspect 2000;32:132-7.									
% seek	52.0%	3,120,530	Greil AL, McQuillan J. Help-seeking patterns among subfecund women. J Reprod Infant Psyc 2004;22:305-19.									
% obtain	31.4%	1,884,320	Stephen EH, Chandra A. Use of infertility services in the United States: 1995. Fam Plann Perspect 2000;32:132-7.									
% HSG	63.0%	1,187,122	<a href="http://www.obgyn.net/women/women.asp?page=/industry/articles/980318_fall">http://www.obgyn.net/women/women.asp?page=/industry/articles/980318_fall</a>									
International estimates: <a href="http://humrep.oxfordjournals.org/content/22/6/1506.full#ref-28">http://humrep.oxfordjournals.org/content/22/6/1506.full#ref-28</a>												

# Infertility - FAQ



*“What is the value of diagnosing the tubes if no treatment exists?”*

1. The less accurate, more painful HSG procedure is still ordered a **million** times a year, so physicians see value in diagnosing the tubes.
2. No treatment exists because **no direct visualization option** exists. Once we know what causes occlusion, we can start creating therapeutic products.
3. Tubal disease **reduces the chance of IVF success by more than 10%**.
4. Create a **billable procedure** for the gynecologist.

*“What is the use of the nVision device if physicians are going straight to IVF?”*

1. Physicians **are not** going straight to IVF – procedure is ordered a million times a year.
2. Tubal health impacts IVF success rate **by more than 10%**.
3. IVF **is not** improving – most people cannot afford IVF and younger physicians are looking for alternatives.



# Ovarian Cancer

# Lethal and undetectable



22,280 new cases of ovarian cancer were diagnosed and 15,500 women died of ovarian cancer in the United States in 2012

Ovarian cancer is usually found too late because:

- Asymptomatic at early stages
- “Radiology tests (CT scan, MRI) do not provide enough information by themselves to definitively diagnose ovarian cancer” – AMS
- Biopsy of ovary not performed b/c it risks spreading the cancer

Today, the only way to diagnose ovarian cancer with certainty is with a risky, exploratory operation.

## Latest research



National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov

## BENCHMARKS

*An online publication for reporters covering cancer and the National Cancer Institute*[Go to Benchmarks Archive](#)

search

+ SHARE ...

## Ovarian Cancer and Origins in the Fallopian Tubes

## SUBSCRIBE

Subscribe for updates from the office of media relations:

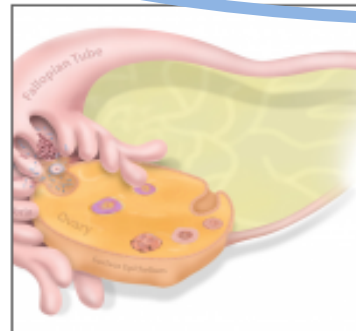


## CATEGORIES

Select Category ▼

## USEFUL RESOURCES

NCI NewsCenter



Ovarian cancer arises in the fallopian tube. Credit: Drapkin

JUNE 6, 2011, 11:00AM

By Linda Perrett

POSTED IN: [Ovarian cancer](#) | [SPOREs](#) | [screening](#)TAGS: [BRCA](#), [fallopian tube](#), [p53](#), [PLCO](#), [precursor lesions](#), [serous cancer](#), [SPORE](#)

Ovarian cancer kills an estimated 14,000 American women each year. The high mortality rate for women with ovarian cancer stems from a lack of early symptoms or screening methods for the disease. As a result, most ovarian cancer patients are diagnosed with advanced-stage disease as highlighted by the findings from the National Cancer Institute's Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial, or [PLCO](#) trial, presented at the annual American Society of Clinical Oncology meeting June 4, 2011.



# nVision's Solution & Product



In the last year and a half, conclusive evidence has surfaced demonstrating that the most lethal forms for ovarian cancer begin in the fallopian tubes.

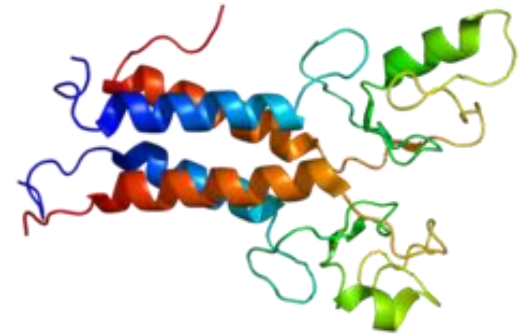


nVision has developed proprietary linear everting balloon technology to access and sample the length of the tube for cancerous cells.

# High-risk patient population

The device is for patients who are at high risk for ovarian cancer.

- Family history of ovarian, breast, endometrial (uterine) cancer
- BRCA1 or BRCA2 mutation
- Family history of Lynch syndrome (hereditary nonpolyposis colorectal cancer [HNPCC])
- Other: never being pregnant, obesity



# Population with risk factors

Risk	# of Patients
Breast cancer	3,000,000
First degree relative with breast cancer	12,200,000
BRCA mutation	780,000-1,200,000
Ovarian cancer	22,280
<b>Total</b>	<b>16.4M</b>

The above numbers are from the National Cancer Institute. For detailed references, please see slide 31.

# Multi – Billion Market

Material cost is approximately \$25. Price the catheter at **\$500**.

## **Assumptions**

- Only **8,000,000** out of the 16,000,000 high risk patients undergo this test
- Every year after 30\*, these patients come in for this test one a year until they are 70 (**40 years** of testing per patient total)

8,000,000 patients annually X \$500 per catheter

# \$4B Market Opportunity

Annually, in the US alone

\*Current guidelines dictate that these same high risk patients come in every six months for a transvaginal ultrasound and a blood test to look for CA-125 elevation. Both of these tests are poor indicators.

# Regulatory & Reimbursement

- 510(k) Class II device – substantial equivalence to SSG catheter & nVision infertility device
- CE Mark: Class II device
- ICD -9 and CPT Codes exist for diagnosing ovarian cancer

## CPT CODES\*:

Test code 16991(X): 84999

Test code 16992(X): 84999, 83001, 83002

## ICD-9 CODES\*\*:

789.33 Abdominal or pelvic swelling, mass, or lump; right lower quadrant

789.34 Abdominal or pelvic swelling, mass, or lump; left lower quadrant

# Ovarian Cancer References



## **Slide 8 (market /patient population evaluation)**

1. NCI SEER 2009 <http://seer.cancer.gov/statfacts/html/breast.html>
2. NCI PDQ® Cancer Information Summary. National Cancer Institute; Bethesda, MD. Genetics of Breast and Ovarian Cancer (PDQ®) - Health Professional. Date last modified 04/24/2009. Available at: <http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/healthprofessional>.
3. <http://inthefamily.kartemquin.com/content/brca-101>
4. National Cancer Institute. *SEER Cancer Statistics Review*, 1975–2005. Retrieved April 20, 2009, from: [http://seer.cancer.gov/csr/1975\\_2005/index.html](http://seer.cancer.gov/csr/1975_2005/index.html).  
<http://cancerres.aacrjournals.org/content/66/16/8297.full> for Number of BRCA mutations in general population

## **All other slides**

- [http://www.uptodate.com/contents/ovarian-cancer-diagnosis-and-staging-beyond-the-basics?source=outline\\_link&view=text&anchor=H11168982#H11168982](http://www.uptodate.com/contents/ovarian-cancer-diagnosis-and-staging-beyond-the-basics?source=outline_link&view=text&anchor=H11168982#H11168982)
- <http://www.uptodate.com/contents/ovarian>
- <http://jama.jamanetwork.com/article.aspx?articleid=1383232>
- <http://www.myhealthnewsdaily.com/139-the-10-deadliest-cancers-and-why-theres-no-cure-.html>
- <http://ww5.komen.org/BreastCancer/GeneMutationsampGeneticTesting.html>
- <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA#r10>
- <http://www.ovariancancer.org/about-ovarian-cancer/statistics/>
- <http://benchmarks.cancer.gov/2011/06/ovarian-cancer-and-origins-in-the-fallopian-tubes-2/>
- <http://seer.cancer.gov/statfacts/html/breast.html>
- <http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/healthprofessional>
- <http://cancerres.aacrjournals.org/content/66/16/8297.full>
- [http://seer.cancer.gov/csr/1975\\_2005/index.html](http://seer.cancer.gov/csr/1975_2005/index.html)
- [http://seer.cancer.gov/csr/1975\\_2005/results\\_single/sect\\_01\\_intro.28pgs.pdf](http://seer.cancer.gov/csr/1975_2005/results_single/sect_01_intro.28pgs.pdf)
- <http://www.ovariancancer.org/about-ovarian-cancer/statistics/>
- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm?GMPPart=884>